# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## effect of laser therapy in reducing of cognitive symptoms, anxiety and depression in patients with mild and moderate dementia

## Protocol summary

**Study aim**
Therapeutic effects of low-level laser therapy in reducing of cognitive symptoms, anxiety and depression in patients with mild and moderate dementia

**Design**
A clinical trial with a control group with two-way randomized parallel groups on 24 patients. Block randomization is used for randomization.

**Settings and conduct**
In the Memory Clinic of Taleghani Hospital, patients will enter the study after obtaining consent from both the patient and the family, and the psychologist (non-blind) will collect their information based on age, gender, level of education, marital status, and the duration of the onset of the disease, presenting symptoms and the level of depression and anxiety through a questionnaire. He takes notes and divides them homogenously into two treatment and control groups and finally gives the information obtained from the questionnaires to the (blind) researcher to be analyzed.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Dementia patients aged 65 years or older who have been diagnosed with dementia for at least 2 years and are under treatment. exclusion criteria: patients with other major psychiatric disorders, history of severe head trauma, claustrophobia, drug use, benzodiazepines use, and those who have significant changes in symptoms and medication regimen in the last 6 months.

**Intervention groups**
The group is treated with low power laser for 2 weeks and 3 sessions of 20 minutes each week, the control group has the device on their head but it is turned off. The level of anxiety and depression and cognitive symptoms in the first and sixth session and one month later are compared between the groups using the evaluation questionnaire and the results before and after.

**Main outcome variables**
Anxiety(Hamilton's questionnaire); depression (GDS questionnaire);Cognitive symptom(MMSE questionnaire)

## General information

**Reason for update**
lack of patient

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20220614055175N1**
Registration date: **2022-12-12, 1401/09/21**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-30, 1402/07/08**
Update count: **1**

**Registration date**
2022-12-12, 1401/09/21

**Registrant information**

**Name**
Somayeh Jarrahi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 21 8888 7176

**Email address**
jarrahi1364@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2022-11-22, 1401/09/01

**Expected recruitment end date**
2024-03-18, 1402/12/28

**Actual recruitment start date**
empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

effect of laser therapy in reducing of cognitive symptoms, anxiety and depression in patients with mild and moderate dementia

**Public title**

Therapeutic effects of low-level laser therapy in reducing of cognitive symptoms, anxiety and depression in patients with mild and moderate dementia Compared with the control group

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients with with mild and moderate dementia who have been diagnosed for at least two years Age over 65 years. Both genders

**Exclusion criteria:**

Patients with a history of major psychatric disorder clastrophobia substance use benzodiazepin use People who have significant changes in symptoms and drug regimen in the last 6 months history of sever traumatic brain injury

**Age**

From **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Data analyser

**Sample size**

Target sample size: **24**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The method of randomization is done as block randomization for 24 people. If A is for treatment and B is for control, first we define 6 combinations with equal allocation as follows: 1=(ABBA) 2=(ABAB) 3=(AABB) 4=(BABA) 5=(BBAA) 6=(BAAB) Then, using the table of random numbers from 1 to 6, six numbers are selected and based on the numbers selected from the list above, we determine the order of the patient or the control.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Each patient is assigned a code at the beginning of the study, which will be known by that code until the end of the study. This study was conducted in a double-blind manner, so that the patients, doctors, and clinical caregivers and the data analyzer are not aware of the groupings and only the third party, who is the psychologist of the department It will group people and evaluate relevant questionnaires before and after treatment.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Shahid Beheshti University of Medical Sciences

**Street address**

Taleghani Hospital,kodakyar Street , Student Blvd ,Valenjak

**City**

Tehran

**Province**

Tehran

**Postal code**

1985711151

**Approval date**

2022-10-23, 1401/08/01

**Ethics committee reference number**

IR.SBMU.MSP.REC.1401.349

## Health conditions studied

### 1

**Description of health condition studied**

Dementia

**ICD-10 code**

F03

**ICD-10 code description**

Unspecified dementia

## Primary outcomes

### 1

**Description**

Depression

**Timepoint**

Before and after treatment

**Method of measurement**

Geriatric depression Scale questionnaire

### 2

**Description**

Anxiety

**Timepoint**

Before and after treatment

**Method of measurement**
Hamilton anxiety questionnaire

**3**

**Description**
Cognitive symptom
**Timepoint**
Before and after treatment
**Method of measurement**
minimal mantal status examination

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: This group will be formed by patients who receive PBM (photobiomudulation) as an auxiliary treatment for two weeks and their information is based on age, sex, level of education, marital status and duration of disease onset, cognitive symptoms and depression and anxiety level are noted by the relevant questionnaires and they are treated with low power laser for 2 weeks and 3 sessions every week. The level of depression, anxiety and cognitive symptoms are evaluated again by questionnaire at the end of the treatment and one month after the last treatment when visiting the clinic and the before and after results are compared between the 2 groups.
**Category**
Treatment - Devices

**2**

**Description**
Control group: The people of the second group will be selected as the same control group as the first group. Cognitive symptoms, level of depression and anxiety are evaluated by a questionnaire at the beginning of the treatment, at the last session of the treatment and one month after the last treatment at the clinic and the before and after results are compared between the 2 groups.
**Category**
Treatment - Devices

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Taleghani Hospital
**Full name of responsible person**
Ali Kheradmand
**Street address**
Taleghani Hospital,kodakyar Street , Student Blvd ,Valenjak
**City**
Tehran
**Province**
Tehran
**Postal code**
1985711151
**Phone**
+98 21 2243 2560
**Fax**
+98 21 2243 2570
**Email**
taleghanihospital@sbmu.ac.ir
**Web page address**
http://taleghani.sbmu.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Afshin Zarghi
**Street address**
Student Blvd ,Valenjak
**City**
Tehran
**Province**
Tehran
**Postal code**
1983969411
**Phone**
+98 21 2243 9770
**Email**
info@sbmu.ac.ir
**Web page address**
https://old.sbmu.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Shahid Beheshti University of Medical Sciences
**Proportion provided by this source**
100
**Public or private sector**
Public
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**
Somayeh Jarrahi

**Position**
Resident

**Latest degree**
Medical doctor

**Other areas of specialty/work**
Psychiatrics

**Street address**
Sarshar dormitory number 12,sarshar dead end alley,Valiasr street

**City**
Tehran

**Province**
Tehran

**Postal code**
1961835484

**Phone**
+98 21 2272 1367

**Email**
jarrahi1364@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Shahid Beheshti University of Medical Sciences

**Full name of responsible person**
علی خردمند

**Position**
Associate professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Psychiatrics

**Street address**
Taleqani hospital, Student Blvd ,Valenjak

**City**
Tehran

**Province**
Tehran

**Postal code**
1985711151

**Phone**
+98 21 2243 2560

**Fax**
+98 21 2243 2570

**Email**
dr.alikheradmand@yahoo.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Shahid Beheshti University of Medical Sciences

**Full name of responsible person**
Somayeh Jarrahi

**Position**
Resident

**Latest degree**
Medical doctor

**Other areas of specialty/work**
Psychiatrics

**Street address**
Sarshar dormitory number 12,sarshar dead end alley,Valiasr street

**City**
Tehran

**Province**
Tehran

**Postal code**
1961835484

**Phone**
+98 21 2272 1367

**Email**
jarrahi1364@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available

**Study Protocol**
Yes - There is a plan to make this available

**Statistical Analysis Plan**
Yes - There is a plan to make this available

**Informed Consent Form**
Yes - There is a plan to make this available

**Clinical Study Report**
Yes - There is a plan to make this available

**Analytic Code**
Yes - There is a plan to make this available

**Data Dictionary**
Yes - There is a plan to make this available

**Title and more details about the data/document**
All data can potentially be shared after de-identifying individuals

**When the data will become available and for how long**
Access starts 6 months after the results are published

**To whom data/document is available**
All researchers working in academic and scientific institutions, doctors and pharmaceutical companies will be allowed to access the information

**Under which criteria data/document could be used**
The applicant can access the information after providing proof of identity

**From where data/document is obtainable**
Applicants can contact Dr. Somayeh Jarrahi by email to receive the desired documents or data.jarrahi1364@gmail.com

**What processes are involved for a request to access data/document**
The applicant can communicate with the researcher through email and receive the basic data after presenting the identity documents

**Comments**